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September 27, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket #2004N-0081, Use of Materials Derived From Cattle in Human Food and Cosmetics

To Whom It May Concern:

On behalf of Farm Sanctuary and its 100,000 members, I wish to comment on the FDA's interim final rule on the Use of Materials Derived From Cattle in Human Food and Cosmetics, published in the *Federal Register* on July 14, 2004.

The interim final rule identifies five categories of materials to be prohibited from human food and cosmetics: 1) specified risk materials from certain cattle, 2) small intestine of all cattle, 3) material from non-ambulatory disabled cattle, 4) material from cattle not inspected and passed for human consumption, and 5) mechanically separated beef.

Farm Sanctuary strongly supports the proposed definition of non-ambulatory disabled cattle and the prohibition on the use of materials from these animals in dietary supplements and cosmetics. We urge the FDA to broaden this prohibition to include materials from all species of non-ambulatory livestock. Furthermore, Farm Sanctuary supports a prohibition on the use of specified risk materials (SRMs) for food and recommends that all cattle intestines be included in the ban and that the ban be extended to SRMs from animals of all ages, not just those 30 months and older. The rationale for these recommendations is given below.

1. All non-ambulatory cattle should be excluded from the food supply.

It is generally agreed that non-ambulatory cattle are more likely to be infected with BSE than healthy cattle and therefore pose a greater risk to public health. During surveillance testing for the disease, BSE has been found to be more common in downed than healthy cattle. For example, in BSE testing conducted in Germany in 2001, positive samples were

detected in 0.48 percent of sick cows, compared with 0.02 percent of dead cows, and 0.002 percent of normal cows.

All downed animals must be excluded from the food supply because government slaughterhouse veterinarians are unable to determine by visual examination whether an animal is safe to be slaughtered. Conditions that present the most serious risk to public health – namely, bacterial contamination and central nervous system disorders like BSE – are difficult to diagnosis solely on the basis of a cursory physical examination. The signs of BSE often cannot be differentiated from the signs of the many other diseases and conditions affecting downer cattle. The Harvard Center for Risk Analysis estimated that up to 50 percent of BSE cases could be missed on ante-mortem inspection at slaughter.

Furthermore, testing every downed animal for BSE would not necessarily provide adequate protection because it is possible that a different variant of the disease is currently present – or at some point may be present – in the U.S. Individual laboratory tests have failed to detect the disease under certain circumstances. For example, the laboratory test currently employed by the USDA failed to detect the disease when used recently by authorities in Japan.

The fact that downed animals are at a higher risk for BSE, and that visual examination and laboratory testing cannot detect the disease with certainty, are the primary reasons typically cited for banning materials from downed cattle in the human food supply. However, there are several other notable arguments for prohibiting the use of materials from non-ambulatory animals, including the following:

- Ban protects the public from other foodborne disease – While the stated objective of the interim final rule is to minimize human exposure to the BSE agent, prohibiting downed animals from the food supply will also eliminate a source of other foodborne diseases. Research has documented a relationship between non-ambulatory status and the presence of pathogens in cattle. For example, E. coli has been found to be more common in non-ambulatory versus healthy cows at slaughter (*Applied and Environmental Microbiology*;2003;69: 4683). In addition, outbreaks of Salmonella Newport, a strain of Salmonella resistant to antibiotics, have been traced back to meat produced from slaughtered dairy cows and to processing plants that slaughter a higher proportion of downed animals (*New England Journal of Medicine*;1987;316:565; *Journal of the American Medical Association*;2002; 288:951).

- Ban lessens animal suffering – Due to their size and weight, it is very difficult to move a downed cow humanely. Non-ambulatory animals are frequently subjected to unnecessary pain and distress during movement from one location to another. This mistreatment often results in injuries ranging from bruises and abrasions to broken bones and torn ligaments. Downed animals that leave the farm rarely receive veterinary attention. Stockyards are reluctant to call veterinarians because they do not own the animals, and don't want to be financially responsible for services rendered. Because downers are immobile, they cannot get to food and

water. They may lie for hours or even days without having their most basic needs met, and many die of gross neglect.

- Ban provides incentive for better animal treatment – Prohibiting the marketing of non-ambulatory animals provides an economic incentive for better animal handling. Dr. Temple Grandin, livestock expert and professor at Colorado State University, has observed that 5-10 percent of the dairies are responsible for 90-95 percent of downed dairy cows (*AWIC Bulletin*;1998;9(1-2). This implies that a vast majority of downers are preventable. In fact, Dr. Grandin has estimated that 75 percent of all downed cattle could be prevented by good management (*Journal of the American Veterinary Medical Association*;1994;204:372).

- Industry supports a ban – A number of agriculture industry groups, including the American Farm Bureau, the American Meat Institute, the National Cattlemen's Beef Association, the American Veal Association, the Milk and Dairy Beef Quality Assurance Center, and the National Pork Producers Council, have recommended that non-ambulatory animals be euthanized on the farm and not transported to market. These groups recognize the negative impression conveyed by downers being dragged to slaughter, and they also appreciate that preventing animals from going down, by taking better care of them in the first place, is ultimately good for business. In a survey of readers of the industry newsletter *Cow-Calf Weekly*, 80 percent of respondents agreed with the USDA ban on marketing of non-ambulatory cattle (*Beef Cow-Calf Weekly*;1/6/04).

- Ban has minimal economic impact – Many in the meat industry are not opposed to ending commerce in downers because they recognize that such a move would have little economic impact on farmers. According to an article in *Dairy Herd Management*, cull cow sales account for only 4 percent of the annual income of dairies. In studying the slaughter of non-ambulatory cattle in California, Dr. Pam Hullinger of the California Department of Food and Agriculture found that, on average, only $28.70 profit was realized for each downed cow leaving the farm (1999 Report of the Committee on Animal Health, U.S. Animal Health Association).

- Public supports a ban – Prior to the discovery of BSE in December 2003, most Americans were unaware that non-ambulatory animals were routinely slaughtered for human food. National public opinion polls conducted by Zogby International in 2001 and 2003 for Farm Sanctuary have shown that a large majority of Americans are opposed to using downed animals for human food. In the 2003 survey, 77 percent of those surveyed indicated they felt slaughtering animals too sick to stand or walk was unacceptable.

- Local and state bans already in place – In the past decade, five states (California, Colorado, Indiana, Oregon, and Washington) have enacted legislation restricting the transportation and/or marketing of non-ambulatory animals. In addition, many large slaughter facilities across the country have voluntarily stopped accepting

downed animals due to the animal suffering involved, the safety risk to employees, and the negative public perception.

2. Definition of non-ambulatory cattle should not be changed to exclude animals down due to injury.

The proposed definition of non-ambulatory cattle is "cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions." It is important that this definition not be changed to exclude those animals thought to be down due to injury alone. As mentioned earlier, it is difficult to determine the cause of an animal's non-ambulatory condition. In addition to obvious injuries, the animal may be suffering from a not so obvious metabolic condition. It may be incorrectly assumed that an animal is down due to injury when, in fact, the reverse is true and the injuries were caused by the animal going down due to an undiagnosed health problem. Prohibiting the marketing of all downers will also encourage producers to improve the handling of animals to ensure that they don't become injured.

3. Prohibition on downers should be extended to all livestock.

It has been known since the 1940's that sheep in the U.S. harbor "scrapie," a form of transmissible spongiform encephalopathy (TSE). In addition, there are reports of pigs harboring an apparent TSE at an Albany, NY slaughterhouse in the 1980's. To date, surveillance efforts in the U.S. to detect TSEs have been inadequate. We have failed to test an appropriate number of animals to determine the extent to which U.S. livestock species may be infected. It is indeed possible that mad cow disease has been spreading in the U.S. for at least a decade.

In addition to the BSE variant recently discovered in the Washington State cow, there are likely other variants of BSE afflicting cattle, and other poorly understood or unidentified TSE variants affecting other livestock species. An atypical form of BSE has been detected in a 23-month-old bull in Japan as well as two cattle in Italy. Research published by Dr. Richard Marsh in 1993 suggested "the presence of an unrecognized BSE-like disease in the United States," while an article published by R.C. Cutlip et al in the *Journal of Infectious Diseases* (1994;169:814) suggested that the agent causing scrapie in sheep could cause neurological disease in cattle.

Variants of BSE or other TSEs may be linked to cases of classical Creutzfeldt-Jakob Disease (CJD) in the U.S. and elsewhere. A study by French scientists, published in 2001 (*Proceedings of the National Academy of Sciences*; 2001;98:4142), found a strain of scrapie also caused brain damage in mice similar to the classical form of CJD in humans. In another study conducted in Great Britain, scientists injected BSE into mice whose brains had been genetically engineered with human genes. One group of mice became ill with the human form of mad cow, referred to as the new variant CJD. These two studies suggest that some of the hundreds of Americans who contract classical CJD each year could have been infected by BSE or TSE-infected meat.

It is indeed possible that some cases of CJD in the U.S. are caused by eating meat from sheep suffering from scrapie. Speculation exists that pigs may also harbor mad cow disease and pass it on to humans. It is known that pigs are susceptible to the disease; research has shown that pigs can be infected by mad cow brains (*Veterinary Record*; 1990;127:338). Epidemiological studies have also suggested a link between sporadic CJD and pork consumption. One study (*American Journal of Epidemiology*; 1985;122:443) analyzed peoples' diet histories and found that those who included ham in their diet appeared 10 times more likely to develop CJD than those who didn't eat ham. The researchers concluded, "The present study indicated that consumption of pork as well as its processed products (e.g., ham, scrapple) may be considered as risk factors in the development of Creutzfeldt-Jakob disease."

An article published in the *National Hog Farmer* in February 2002 estimated the number of crippled hogs presented at slaughter in the U.S. as 420,000/year. If pigs do in fact harbor mad cow disease, these disabled animals represent those at highest risk for transmitting the disease to people. Given the research suggesting a link between TSEs in animals other than cattle and cases of CJD in humans, it appears appropriate to prohibit the slaughter of all non-ambulatory animals, not just cattle.

4. Prohibited cattle materials should include the entire intestines of all cattle.

The interim final rule excludes the small intestine of all cattle from human food. However, the European Union has identified the entire intestine, from duodenum to rectum, as specified risk material and prohibits its inclusion in the food supply of member nations (*Journal of the European Communities*, December 2000). According to the Scientific Steering Committee of the European Union, the intestine should be considered a primary source of infectivity since BSE infection has been caused by cattle ingesting contaminated feed. In classifying the entire intestine as SRM, the EU Steering Committee also notes that because slaughterhouse contamination of other intestinal areas with matter from the ileum can't be avoided, it is prudent to remove the entire small and large intestine.

5. Prohibited cattle materials should include specified risk materials from cattle of all ages.

The interim final rule prohibits the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (with exceptions), and the dorsal root ganglia of cattle 30 months of age and older from human food. However, because only about 15 percent of cattle slaughtered in the U.S. are over 30 months of age, this allows the brains and other central nervous tissue from 30 million animals a year to enter into the human food supply.

The age at which cattle develop clinical BSE varies and the lower ranges of this age distribution includes some cattle younger than 30 months of age. In fact, at least two confirmed cases of BSE in Japan have occurred in animals under 30 months of age. A total ban on SRM, regardless of age of the animal, would best protect the public since a

blanket ban would significantly improve enforcement and eliminate the need to determine the age of each animal. Until a national animal identification and tracking system is fully implemented, USDA personnel will be responsible for determining age. If the appropriate records are unavailable or unreliable, USDA officers will be required to make a physical assessment to determine age. Such an assessment is somewhat subjective. Even with an animal identification system, errors are possible. Furthermore, it is more efficient to process all carcasses in a similar manner than identifying and segregating parts coming from animals of a certain age. Therefore, we recommend that SRMs from animals of all ages be excluded from the human food supply.

Conclusion

Farm Sanctuary commends the FDA for taking action to end the use of materials from non-ambulatory cattle in human food and cosmetics. There is a strong connection between the treatment of animals raised for food and public health. Therefore, in order to further promote the protection of both humans and animals, we urge the FDA to finalize the ban and extend it to materials from all non-ambulatory animals, not just cattle.

Thank you for allowing Farm Sanctuary the opportunity to comment on a matter of great importance to our members.

Sincerely,

Gene Bauston, President
Farm Sanctuary, Inc.